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Atty. Dkt. No.: 8325-0034 Client Dkt. No.: S34-US1

#### **REMARKS**

#### Status of the Claims

Claims 1-15 were pending. Claims 1 and 6-15 were withdrawn from consideration pursuant to a Restriction Requirement that has been made FINAL and claims 2-5 were examined. By amendment herein, claims 1 and 2 have been amended to make explicit what was previously implicit, namely that the sequences of the array consist of sequences corresponding to accessible regions. Because the amendments do not add new matter and do not required additional searches, entry thereof after final is requested.

## **Notice of Non-Compliant Amendment**

The amendment after final was alleged to be non-compliant on the grounds that withdrawn claims were not canceled. See, Continuation Sheet of Notice of Non-Compliant Amendment, citing MPEP § 821.01. In addition, the Examiner alleged that Applicants had made a statement saying the Restriction Requirement had not been made Final. *Id*.

When claims are not found allowable, there is no requirement to cancel non-elected claims where the election was made with traverse. MPEP § 821.01. As long as a Notice of Appeal has not been filed, Applicants retain the right to petition the Restriction Requirement. Accordingly, withdrawn claims do not have canceled in response to a final rejection, but can be maintained, for example by filing of an RCE, in order to preserve the right to petition the Restriction Requirement. Furthermore, Applicants clearly noted in their Response After Final their understanding that the Restriction Requirement had been made FINAL. See, first paragraph of section entitled "Restriction Requirement" in Response After Final and in instant paper. Thus, the Notice of Non-Compliant Amendment was improper and, in any event, is rendered moot by the filing of this submission.

#### **Restriction Requirement**

As noted above the Restriction Requirement as between 10 allegedly distinct groups has been made FINAL. (Final Office Action, paragraph 1) on the grounds that U.S. Patent No. 5,474,796 (hereinafter "Brennan") discloses arrays as claimed. *Id*.

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In fact, Brennan does not disclose arrays <u>as originally, previously or now claimed</u> because Brennan's arrays are **not** made up solely of sequences obtained from accessible regions as claimed. In other words, while Brennan's arrays may "comprise" the sequences on the claimed arrays, they cannot anticipate the claimed arrays because Brennan's arrays also <u>necessarily</u> include additional (non-accessible) sequences that are excluded from the scope of the claims (original, previously pending and as amended). Thus, as determined by the International Search Authority, all claims share a special technical feature (arrays made up only of sequences consisting of sequences corresponding to accessible regions of cellular chromatin) that is novel over Brennan. Hence, unity of invention is present and the Restriction Requirement should be withdrawn.

Applicants again expressly reserve their right to petition the Restriction Requirement. Furthermore, Applicants reserve the right to rejoinder of method claims depending from the elected composition claims and also reserve their right under 35 USC §121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application.

### **Information Disclosure Statements**

Applicants note with appreciation return of the signed PTO/SB/08A forms indicating the references submitted with the Information Disclosure Statement received on December 4, 2007 have been considered.

#### Rejections Withdrawn

Applicants note that the objections to the specification (for embedded hyperlinks) and the rejection of the claims under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph have been withdrawn.

## 35 U.S.C. § 102(b)

Claims 2 to 5 were again rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Brennan. (Final Office Action, paragraphs 5-7). Brennan was cited for disclosing arrays of oligonucleotides that comprise "all possible 10mers." *Id.* at paragraph 6. In addition, it was alleged that because the claims are product by process claims, there is no structural difference

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between the claimed arrays and those disclosed in Brennan. *Id.* at paragraph 7. In response to Applicant's previous arguments that Brennan does not inherently disclose the claimed arrays, the Examiner stated (Final Office Action, paragraphs 9 and 10, emphasis in original):

It is noted that the claims are drawn to an array, which is claimed in terms of product-by-process. The claims do not recite any specific size or nucleotide composition/sequence. Brennan teaches an array of oligonucleotides that comprises all possible oligomers of a given size. As such, Brennan teaches each and every possible sequence for every accessible region of all possible cellular chromatin.

While argument has been presented that "the chance that an array of synthetic 10-mers would represent the same sequences corresponding to accessible regions is astronomically small," just the opposite is the case as the array of Brennan comprises all possible oligomers, and as such would, by default, comprise each and every sequence of the now claimed array. In fact, it is impossible that the array of Brennan would not comprise just such sequences. Further, applicant's representative has presented no evidence of record that shows that an array that comprises all possible sequences could not comprise the now claimed sequences.

In the Advisory Action, it was asserted that the term "accessible region" includes any sequence that does not have a typical nucleosome structure and, accordingly, Brennan's synthetic, naked 10-mers were "considered to meet this requirement." (Advisory Action, continuation sheet).

Applicants again traverse the rejection and supporting remarks.

For the reasons of record, Applicants again note that the evidence of record clearly and unambiguously establishes that an array comprising all possible 10-mers cannot anticipate an array as claimed, in which <u>every</u> sequence on the array consists of sequences <u>corresponding</u> to an accessible region of cellular chromatin.

As defined in the specification, accessible regions are those regions of endogenous cellular chromatin that do not have a typical nucleosome structure. Thus, the claimed sequences are those that, as isolated from endogenous chromatin, <u>correspond</u> to sequences that do not have a typical nucleosome structure. The "corresponding to" limitation is important – the sequences actually fixed to the claimed arrays do not contain any nucleosome or other chromatin structure. Rather, the sequences on the array are naked DNA sequences corresponding to the sequence of

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an isolated accessible region. By contrast, the oligos of Brennan's arrays do <u>not</u> consist of sequences corresponding to accessible regions. It is nonsensical to assert that arrays including all possible 10-mers are necessarily sequences "corresponding to" accessible regions on the grounds that these 10-mers do not have a typical nucleosome structure. The fact remains that both arrays will have naked DNA, but only in the claimed arrays will each and every sequence correspond to a sequence of an accessible region. Simply put, the claimed arrays and Brennan's arrays are, by any definition, different arrays.

Thus, the assertion that the process limitations of the claims (isolated sequences corresponding to accessible regions) fail to impart structural distinctions is completely untenable. As previously noted, product-by-process claims are completely proper and undeniably patentable when the process steps impart distinctive structural characteristics to the final product. See, e.g., MPEP § 2113. In the instant case, an array of sequences consisting of sequence corresponding to accessible regions is structurally distinguishable from Brennan's arrays because the claimed arrays include only sequences corresponding to accessible regions. By contrast, Brennan's arrays necessarily include both sequences corresponding to accessible regions and sequences corresponding to non-accessible regions. Moreover, the recited process steps (isolation of sequences corresponding to accessible regions) clearly impart the claimed structural distinction (array consisting of only accessible regions as compared to arrays including all 10-mers that inevitably include both accessible and non-accessible sequences).

Therefore, because Brennan does not disclose all the elements of the claims and because the evidence or record clearly establishes that the recited process steps impart structural limitations that distinguish the claims from the arrays of the cited reference, Brennan cannot anticipate any of the pending claims and withdrawal of the rejection is in order.

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# **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that all of the pending claims are in condition for allowance and request early notification to that effect.

Should the Examiner have any further questions, Applicants request that the undersigned be contacted at (650) 493-3400.

Respectfully submitted,

Date: May 12, 2008

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